IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OKLAHOMA

In re: Genentech, Inc., Herceptin (Trastuzumab) Marketing and Sales Practices Litigation	)	MDL Docket No. 16-MD-2700
	)	Document Relates to: **All Cases**

PLAINTIFFS' FIRST APPLICATION TO REMOVE CONFIDENTIAL DESIGNATION FROM GENENTECH PRODUCED DOCUMENTS AND INFORMATION

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Genentech performs dual functions. It performs innovative research and it is a run-of-the-mill merchant peddling its innovations. In its scientific role, Genentech manufactures Herceptin using a process that converts certain animal cells into a very powerful cancer-fighting medicine. None of the documents placed at issue by this motion provides any information about how Genentech's process works, or adds to the public record any additional information about the constituents used in the process.

In its merchant role, Genentech, like other merchants who peddle tooth paste, peanut butter, ketchup, diamonds, water or any other product, tests its products before shipping them to the public. These tests determine that certain characteristics like color, pH and weight match Genentech's standards. If the lot conforms to this relatively standard quality control testing, the lot is shipped to a healthcare provider.

This motion challenges Genentech's claim that the results of this merchant function are secret because the process of converting animal cells into a drug is secret. Genentech's claim is nothing more than an attempt to withhold as secret the uncomfortable fact that the test results confirm plaintiffs' fundamental allegations in this case. Moreover, not only is the motivation improper, but the logic is missing. When Genentech releases its medicine into the stream of commerce (for a substantial profit) any reputable lab can recreate all of the measurements Genentech seeks to hide by testing any of the shipped medicine.

In short, Genentech is misusing the Protective Order to prevent commercial embarrassment. Plaintiffs ask this Court to remove the improper confidentiality designations on the documents listed below.

Background

Early in this litigation, the parties agreed that "to expedite the flow of discovery material and to preserve the confidentiality of *certain documents and information*, a protective order should be entered by the Court." Protective Order at 1 (Dkt. #43) (emphasis added). The parties did not agree, however, that all documents and information exchanged in this case would, by default, be designated as "Confidential." In accordance with Federal Rule of Civil Procedure 26(c), the parties agreed only documents and information that "constitute, reflect or disclose trade secret or other confidential research, development, or commercial information" would be treated as confidential in connection with this lawsuit. Protective Order § 1.b. (Dkt. #43). Nonetheless, Genentech has designated over 90% of its produced documents as "Confidential" or "Highly Confidential."[1]

Close evaluation of Genentech's designations reveals that Genentech improperly designated numerous documents, including those listed in Exhibit 1. Pursuant to Paragraph 8 of the MDL Protective Order, Plaintiffs file this Application to remove Genentech's errant confidential designations on documents discussing the amount of Herceptin in vials shipped to providers and documents exchanged between FDA and Genentech. Plaintiffs seek removal of the confidential designations on the following items:

[1] As of today, Genentech has produced approximately 802 documents. 469 are designated "Highly Confidential." 254 are designated "Confidential." Only 79 are not designated as either Confidential or Highly Confidential, primarily the Herceptin labels, cartons, and physician inserts.

Table 1: Objections Regarding
Confidential Designations for Amount of Herceptin in Shipped Vials

Document	Citation	Exhibit #
REDACTED HEARING TRANSCRIPTS		
8/3/16 Hrg. Tr.	7:16	2
8/3/16 Hrg. Tr.	52:18	2
8/3/16 Hrg. Tr.	Index p. 1	2
11/17/16 Hrg. Tr.	16:10-14	3
11/17/16 Hrg. Tr.	43:10-12	3
11/17/16 Hrg. Tr.	43:17-18	3
SEALED FILING		
Table attached to Dana L. Swisher's Declaration	Dkt. No. 108-4 at pp. 6-11	4
PRODUCED DOCUMENTS		
Dec. 5, 2014 Genentech Response to FDA Comments	GENE-REG000000118-GENE-REG000000128	5
Certificates of Analysis	GENE-PS000000045-GENE-PS000000813	6

(Exhibit 1, Table of Objections Regarding Amount of Herceptin in Shipped Vials). Plaintiffs request removal of (1) redactions from portions of the August 3, 2016 and November 17, 2016 Hearing Transcripts (Exhibit 2, Aug. 3 Tr. Excerpts, and Exhibit 3, Nov. 17 Tr. Excerpts) (collectively, the "Hearing Transcripts"); (2) confidentiality designation on a table listing the amount of Herceptin in lots shipped from Genentech attached to the Declaration of Dana L. Swisher (the "Swisher Table") offered in support of Genentech's Motion for Summary Judgment (Exhibit 4, Swisher Table); (3) confidentiality designations from a 2014 Genentech Response to FDA Comments (Exhibit 5, 2014 Genentech Response to FDA Comments); and (4) confidentiality designation from the Certificates of Analysis ("COAs") showing the actual amount of Herceptin contained in all shipped lots since 2010. (Exhibit 6, Sample COA). These documents reference the amount of Herceptin in vial or lots shipped to the public. After consultation Plaintiffs and

Genentech have not resolved Genentech's contested assertion that the amount of Herceptin in shipped vials is a trade secret.

Plaintiffs also seek removal of the confidential designations on the 2017 FDA General Advice Letter. (Exhibit 7, 2017 FDA General Advice Letter). After consultation, Plaintiffs and Genentech have not resolved Genentech's contested assertion that this FDA correspondence is confidential commercial information.

Following the Protective Order's process for challenging improper designations, Plaintiffs and Genentech exchanged communications that did not resolve the designation controversy. *See* Feb. 15, 2017 Letter from Keglovits to Donahue (Exhibit 8, Feb. 15 Plaintiffs Letter regarding 2017 FDA General Advice Letter); Feb. 22, 2017 Letter from Keglovits to Donahue (Exhibit 9, Feb. 22 Plaintiffs Letter regarding Amount of Herceptin in Shipped Vials); Feb. 22, 2017 Letter from Donahue to Keglovits (Exhibit 10, Feb. 22 Genentech Letter regarding 2017 FDA General Advice Letter); Feb. 27, 2017 Letter from Donahue to Keglovits (Exhibit 11, Feb. 27 Genentech Letter regarding Amount of Herceptin in Shipped Vials). The parties met and conferred on February 28 via teleconference. Genentech agreed to remove the confidentiality designation on one document – a Letter to the Editor published in The New England Journal of Medicine discussing the Herceptin shortage. Genentech refused to remove all other confidentiality designations challenged by Plaintiffs. The parties confirmed the impasse in writing. *See* Emails between Wes Pebsworth and Alicia Donahue (Feb. 28, 2017) (Exhibit 12, Feb. 28 Meet and Confer Emails)

Genentech's sole justification for the sweeping confidentiality designations fails to meet its burden to overcome the presumption of openness in the judicial process. Genentech argues that the documents are designated confidential "to protect trade secrets" competitors "may copy."

(Exhibit 12, Feb. 28 Meet and Confer Emails). The amount of Herceptin in shipped vials is not a trade secret. The improper designations contravene the Federal Rules of Civil Procedure and interfere with the public's access to judicial proceedings, especially concerning materials proffered by Genentech in support of a summary judgment motion.

The improper designations place an unnecessary burden on Plaintiffs, including requiring Plaintiffs to either carefully redact materials that should not be redacted or file many pleadings under seal. The improper designations also encumber communications between Plaintiffs and their clients as the designations limit communications to either 5 or 2 client representatives depending on the specific designation. The improper designations frustrate the ability of potential class members to assess whether to participate in the case. The improper designations unnecessarily limit communication with fact witnesses, including current and future regulators. And the improper designations restrict FDA's understanding of Genentech's misrepresentations, which affects the FDA-Genentech communications that Genentech wishes to enter into the summary judgment record.[2] Plaintiffs seek an Order from the Court removing the confidentiality designations from the identified documents and ordering Genentech to produce new versions without a confidentiality stamp.

Argument and Authorities

I. Genentech Bears The Burden To Prove Each Document Is Properly Designated.

Genentech must show "good cause" why a filed document should not be accessible by the public. Fed. R. Civ. P. 26(c)(1). To carry its burden to designate documents as confidential, Genentech must prove the information or document designated "is a trade secret [or confidential commercial information] and then demonstrate that its disclosure might be harmful." *Centurion*

[2] *See* Genentech's Motion to Supplemental Summary Judgment Record (Dkt. #173).

Indus., Inc. v. Warren Steurer and Assocs., 665 F.2d 323, 325 (10th Cir. 1981). This requires showing "that disclosure [of the requested information] will result in a clearly defined and serious injury to the party seeking protection." *Ring Energy, Inc. v. Hullum*, No. 15-CV-109-JHP-TLW, 2015 WL 4413366, *6 (N.D. Okla. July 17, 2015).

In this case, the Court entered an agreed-upon Protective Order permitting Genentech to designate materials as confidential without making a showing of good cause. However, if Plaintiffs challenge a designation, Genentech bears the burden to show good cause that materials designated confidential are a trade secret or confidential commercial information:

> **Objections to Designations.** A party may, at any time, make a good faith challenge to the propriety of a Confidential or Highly Confidential Information designation. In the event a party objects to the designation of any material under this Order, the objecting party shall consult with the designating party to attempt to resolve their differences. If the parties are unable to reach an accord as to the proper designation of the material, after giving notice to the designating party, the objecting party may apply to the Court for a ruling that the material shall not be so designated. If such a motion is made, ***the designating party has the burden of establishing that the designation is proper***. If no such motion is made, the material will retain its designation. Any documents or other material that have been designated "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" shall be treated as Confidential and Highly Confidential until such time as the Court rules that such materials should not be treated as Confidential and Highly Confidential.

Protective Order § 8 (emphasis added).

Genentech bears the burden of proving its confidentiality designation is proper. *Id*; *see also Littlebear v. Advanced Bionics, LLC*, 11-CV-418-GKF-PJC, 2012 WL 2979023, *2 (N.D. Okla. July 20, 2012) (party seeking protection of information "must demonstrate that the information sought constitutes a trade secret, or other confidential research, development, or commercial information and then demonstrate that its disclosure might be harmful"); *Pine Telephone Co. v. Alcatel Lucent USA Inc.*, 617 Fed. App'x 846, 852 (10th Cir. 2015) ("The party seeking to overcome the presumption of public access to the documents bears the burden of showing some significant interest that outweighs the presumption."). To carry its burden, Genentech must "come

forth with 'specific examples' of competitive harm" it will suffer if the "Confidential" designations are removed. *Waelde v. Merck, Sharp & Dohme*, 94 F.R.D. 27, 28 (E.D. Mich. 1981). "[V]ague and conclusory allegations of confidentiality and competitive harm" are not enough. *Id.*

During the parties' meet-and-confer communications, Genentech attempted to shift its burden to Plaintiffs by requesting an "explanation as to the relevance to Plaintiffs' claims of any of the [] information or documents that [Plaintiffs] seek to de-designate and publish publicly." (Exhibit 12, Feb. 28 Meet and Confer Emails.) Beyond the obvious relevance of documents Genentech relies upon by attaching them to its Motion for Summary Judgment, Genentech has failed to carry its burden of proof in supporting the erroneous designations. Genentech must prove each document constitutes a trade secret or confidential commercial information.

II. The Amount of Herceptin in Shipped Vials Is Not A Trade Secret Or Confidential Commercial Information.

Genentech's improper designations violate the Protective Order and interfere with the strong public policy in favor of openness and transparency in judicial proceedings. Because Genentech labeled most documents as either "Confidential" or "Highly Confidential," the parties and the Court record become encumbered because most pleadings are subject to the procedure for sealing records from public access. *See* Protective Order § 2.f (Dkt. #43). Genentech's systematic practice contradicts the well-recognized presumption "that the public has a common-law right of access to judicial records." *Pine Telephone*, 617 Fed. Appx. at 851-52 (quoting *Eugene S. v. Horizon Blue Cross Blue Shield of N.J.*, 663 F.3d 1124, 1135 (10th Cir. 2011)). Genentech's argument to support its position that the amount of Herceptin in shipped vials is confidential is:

> . . . that the designations are in place to protect trade secrets from which Genentech's competitors may well be able to determine information from which they may copy or come close to Genentech's currently patented and FDA approved testing, manufacturing process, and formula for Herceptin

(Exhibit 12, Feb. 28 Meet and Confer Emails.) When Plaintiffs asked Genentech to identify the publicly available information that a competitor could combine with the information at issue in the materials marked confidential, Genentech's counsel responded you will need to "trust me." Fortunately, that is not the standard required by law.

A. The Amount of Herceptin in Shipped Vials And Lots Is Public Information.

The amount of Herceptin in shipped vials is neither a trade secret nor confidential commercial information. The Tenth Circuit has adopted the FDA's current definition of "trade secret," defining the term to include "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Anderson v. Dept. of Health & Human Servs.*, 807 F.2d 936, 944 (10th Cir. 1990); *see also* 21 C.F.R. § 20.61(a). Confidential "commercial or financial information" is defined as "valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public." *Id.* at § 20.61(b). The amount of Herceptin in shipped vials is not a plan, not a formula, not a device, and not even a secret.

The actual protein content of the material in the vials is in the public domain. Where information is in the public domain, "'no meritorious claim of confidentiality can be made.'" *Brown v. Perez*, 835 F.3d 1223, 1233 (10th Cir. 2016), as amended on reh'g (Nov. 8, 2016) (quoting *Anderson v. Dep't of Health & Human Servs.*, 907 F.2d 936, 952 (10th Cir. 1990)); *York v. Hartford Underwriters Ins. Co.*, 2002 WL 31465306, at *2 (N.D. Okla. Nov. 4, 2002) ("Information . . . available to the public is clearly not confidential."); *cf. Retiree, Inc. v. Anspach*, 660 F. App'x 582, 589 (10th Cir. 2016) (reversing district court for "clear error" because information "in the public domain" is "not confidential"). In discussions with Plaintiffs, Genentech argued that the actual protein content of the material in the vials is confidential information and

should not be disclosed in pleadings. This argument defies logic. A manufacturer who places a product into the stream of commerce cannot misrepresent the mass of its product, then claim that the actual mass is a trade secret or otherwise confidential. The actual amount of Herceptin in these vials is a matter of public information once the vials are placed into commerce because any qualified scientist could test the vials and determine the specific protein content.[3]

B. The Amount of Herceptin in Shipped Vials And Lots Is No More Confidential Than The Existence of The Manufacturing Specification Range.

Genentech publicly acknowledges that an FDA-approved manufacturing specification range exists. Ex. 2 at 6:15-17 ("So that's the range. And because there's a range of content, there's necessarily a range on the numbers you're referring to on the concentration."). While Genentech asserts the specific range of [redacted] is confidential,[4] it is no secret that a range exists. The actual amount of Herceptin shipped in each vial provides no more competitively useful information than knowing a manufacturing specification exists, particularly considering Genentech's decision to routinely fill its vials below the labeled amount.

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[3] Genentech acknowledges the ability to test for the amount of Herceptin. *See* Def.'s Reply In Support Of Mot. To Dismiss Pls.' First Am. Compl. at 3 (Dkt. #61 in *TCI et al. v. Genentech*, 15-cv-157-TCK-TLW (Nov. 30, 2015)) ("Plaintiffs do not allege that they ever measured the amount of Herceptin . . ."); *id.* at 5 ("Plaintiffs do not allege that they tested the amount of Herceptin powder in vials. . ."); Def.'s Mot. To Dismiss Pls.' Second Am. Compl. at 2 (Dkt. #92 in *TCI et al. v. Genentech*, 15-cv-157-TCK-TLW (Feb. 16, 2016)) ("Plaintiffs have not tested the amount of Herceptin solution the vials contain"); *id.* at 6 ("Plaintiffs have not tested ***any*** Herceptin vials to determine whether they contain 440 mg of Herceptin, either before or after reconstitution."); *id.* at 8 ("Plaintiffs did not test the weight of the Herceptin"); *id.* at 10 ("Plaintiffs never tested how much Herceptin solution the vials ***contain***."); *id.* at 21 ("Plaintiffs never tested how much Herceptin solution the vials contain").

[4] Plaintiffs dispute this confidentiality designation, but that issue is not before the Court at this time.

C. A Heightened Presumption of Openness Applies Because Genentech Relies on The Amount of Herceptin in Shipped Vials to Support Its Summary Judgment Motion.

Genentech relies on the actual amount of Herceptin in shipped lots as support for its Motion for Summary Judgment. The presumption of openness in judicial proceedings is heightened for documents and information presented to support a motion for summary judgment. *Colony Ins. Co. v. Burke*, 698 F.3d 1222, 1242 (10th Cir. 2012) ("[W]here documents are used to determine litigants' substantive legal rights, a strong presumption of access attaches."). Genentech "must articulate a real and substantial interest that justifies depriving the public of access to the records that inform [the Court's] decision-making process." *Id.*; *see also Pine Telephone*, 617 Fed. Appx. at 852 ("The party seeking to overcome the presumption of public access to the documents bears the burden of showing some significant interest that outweighs the presumption.").

Genentech's generic allegations of potential harm are not sufficient to meet its burden of proof to support its improper designations. *See Ring Energy, Inc.*, 2015 WL 4413366, at *6 ("A conclusory allegation is simply insufficient.").

III. Each Document Listed in Exhibit 1 Should Have Its Confidentiality Designation Removed Because The Amount of Herceptin in Shipped Vials Is Not Confidential.

A. The Hearing Transcripts

Genentech redacted portions of two discovery hearing transcripts, memorializing its legal counsel's representations to the Court concerning the amount of Herceptin in shipped vials. For example, Genentech redacted the following statements from the November 17, 2016 discovery hearing transcript:

- Alicia Donahue: "we've produced to them certificates of analysis [redacted] Ex. 3 at 43:10-12 (bold portion was redacted).
- Alicia Donahue: "I mean, we produced our own manufacturing documents [redacted] *Id.* at 43:17-18 (bold portion was redacted).

- David Keglovits: [redacted] *Id.* at 16:10-14 (bold portion was redacted).

Similarly, Genentech redacted portions of the August 3, 2016 hearing transcript:

- William O'Connor, discussing hypothetical protein contents of Herceptin vials: "But it also says, here's the content of the Herceptin. So there's some that say, you know, [redacted], some say [redacted] some say [redacted], whatever it is for every...." Ex. 2 at 7:16 (bold portion was redacted).

- William O'Connor: "It shows the exact—here's one of August 10 of 2012, and the concentration on the content here was [redacted] per vial...." *Id.* at 52:18 (bold portions was redacted)

These statements by counsel are not internal documents. The statements address the amount of Herceptin in hypothetical or actual vials and lots shipped to providers. This information is not confidential commercial information nor is it competitively-sensitive. *See supra* § II. Plaintiffs request the redactions listed in Exhibit 1 be unredacted.

B. The Swisher Table

In support of its Motion for Summary Judgment, Genentech filed a fact-laden declaration sponsored by its employee, Dana Swisher. In addition to a detailed description of Genentech's manufacturing process, Genentech attached to the Motion a table listing the amount of Herceptin in each shipped lot during the past six years. (Ex. 4, Swisher Table). Genentech erroneously marked that Table "Highly Confidential."

The Swisher Table is not confidential commercial information because the information on the table is not secret. The table identifies a Material Number, a specific Batch Number, the Item Lot, and the actual amount of Herceptin in the vials. None of this information is secret or commercially valuable to a competitor.

Genentech's actual motivation in designating this material confidential is not competitive harm, but a desire to conceal from the public, including prospective class plaintiffs and FDA, the

actual amount of Herceptin in vials delivered to providers. For over a decade, Genentech has responded to complaints that providers cannot obtain the warranted 440 mg by accusing providers of user error or pretending the liquid drug sticks to the vial like peanut butter. Genentech has never told the public, including purchasers of the drug or FDA that [redacted]. Genentech is, and should be, concerned with the inevitable revelation that it has misled its customers and FDA. But Genentech's posturing and concealment as to [redacted] is not a legitimate basis for marking the documents and information "Confidential." *See Massey Coal Services, Inc. v. Victaulic Co. of America*, 249 F.R.D. 477, 484 (S.D.W.V. 2008) ("It is possible that these documents may lead to damaging conclusions when considered with other documents or testimony, but that is not the court's concern.").

Plaintiffs request that the Court order the "Highly Confidential" designation be removed from the Swisher Table.

C. The Certificates of Analysis ("COAs")

Genentech produced hundreds of certificates of analysis, which it indirectly relies upon to support its Motion for Summary Judgment. (Exhibit 6, Sample COA). The COAs memorialize testing ranges and the results of quality control testing. Among several quality control tests and results, one piece of information on each COA is the actual amount of Herceptin in the vials to be shipped. The Swisher Table is a compilation of those amounts into a single Table, which Genentech relies upon in its Motion for Summary Judgment.[5]

[5] Plaintiffs' counsel and Genentech's counsel discussed whether redacting portions of the COAs other than the amount of Herceptin in the shipped lots would protect any purported "trade secrets." After consideration, Genentech rejected this approach stating that "any such redactions will not result in a change to the current highly confidential designation." Emails Among David Keglovits,

Like the Swisher Table, the COAs state the actual contents of the Herceptin vials Genentech has placed into commerce, including the amount, the pH level, and the color. Genentech asserts that the COAs are "Highly Confidential" because a competitor may be able to use the information in the COA to figure out how Herceptin is made and reverse-engineer a competing product. Genentech could not, however, identify or explain to Plaintiffs any information on the COAs that may be manipulated by competitors to develop a competing product. Genentech's conclusory "trust me" argument is inadequate to maintain this erroneous designation. *Ring Energy, Inc.*, 2015 WL 4413366, at *6 ("A conclusory allegation is simply insufficient.").

Plaintiffs request that the Court order the "Highly Confidential" designation be removed from the COAs.

IV. FDA Communications Are Not Automatically Confidential Commercial Information.

FDA and Genentech exchanged letters, responses, and teleconference minutes in 2014 and 2017 [redacted]. (Exhibits 5 and 7, Dec. 5, 2014 Genentech Response and 2017 FDA General Advice Letter). Genentech, so far, has designated such FDA related communications as confidential. In the meet-and-confer process, Genentech identified two possible designation justifications: (1) the 2017 FDA General Advice Letter references the Biologics License Application ("BLA"); and (2) the correspondence "concerns a pending regulatory action." Genentech did not, however, articulate a specific competitive harm. The justifications mentioned by Genentech counsel do not qualify the documents a trade secret or confidential commercial information.

The 2017 FDA General Advice Letter's reference to the BLA does not transform the letter into a trade secret. Courts recognize that information included in a New Drug Application (which

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Wes Pebsworth and Alicia Donahue re Certificates of Analysis (Exhibit 13, Mar. 3 Meet and Confer Emails).

is the non-biologic version of the BLA) "is not necessarily a trade secret or confidential commercial information." *Waeide*, 94 F.R.D. at 29. In fact, information like "adverse reaction reports and consumer complaints" and "[s]afety and effectiveness data, which includes 'all studies and tests...of the drug for identity, stability, purity, potency, and bioavailability,'" are not necessarily confidential. *Id.* Genentech must identify why the specific information referenced is confidential commercial information and the specific harm that will result from the information being filed without being sealed.

More generally, courts recognize that correspondence with FDA is not necessarily confidential under Rule 26(c):

> . . . judicial precedent does not afford blanket protection against disclosure of communications with the FDA. Instead, each case turns on its particular facts, and a court will order sealing only where the party resisting disclosure has made a particularized showing of harm that would result from revealing trade secrets

King Pharm., Inc. v. Eon Labs, Inc., 2010 WL 3924689, at *8 (E.D.N.Y. Sept. 28, 2010). Similarly, in *Contratto v. Ethicon, Inc.*, the court considered a request to remove the confidential designation from a group of documents that included "portions of [the defendants'] responses to an FDA deficiency letter," various memorandums related to studies performed by the defendants, "a request to the FDA to supplement the information on the [defendants'] label," various submissions to the FDA, and "letters from the FDA" regarding "changes to the labeling" of a drug, compliance "with applicable FDA regulations," and "information appearing in defendants' promotional materials and on their website which allegedly misrepresent the safety and effectiveness of [the drug]." 227 F.R.D. 304, 307-312 (N.D. Cal. Feb. 7, 2005). The court found that none of those documents was properly designated "confidential" because none "contain[ed] trade secrets or other confidential research, development, or commercial information." *Id.* at 312.

> Simply put, the communication of information to the FDA in connection with a drug application does not automatically trigger protection against disclosure.

> Accordingly, to satisfy their burden of good cause pursuant to Rule 26(c), Elan and King must demonstrate that disclosure of particular information communicated to the FDA would result in a clearly defined and serious injury, and that the asserted harm outweighs the strong common law presumption of public access to the parties' briefs.

King Pharm., Inc., 2010 WL 3924689, at *8.

The same is true of the Dec. 5, 2014 Genentech Response to FDA Comments (Exhibit 5) and the 2017 FDA General Advice Letter (Exhibit 7). Genentech has not demonstrated a clearly defined and serious injury that outweighs the strong common law presumption of public access to the parties' briefs. Accordingly, the confidential designation on these documents should be removed.

Conclusion

Genentech's confidentiality designations must be made in good faith. Genentech's designation of the public letter to the editor in the New England Journal of Medicine illustrates Genentech is not considering each document as it stamps "Confidential."

In the meet-and-confer process, Genentech provided no clearly defined and serious injury that would befall it if these documents were publicly known, much less a serious injury for revealing the actual amount of Herceptin in vials entered into the stream of commerce. Genentech made the erroneously designated material relevant by introducing it and relying upon it to support its Motion for Summary Judgment; yet, Genentech seeks to conceal the material from providers and FDA to ensure those entities do not learn [redacted]. Because Genentech cannot meet its burden to show the actual amount of Herceptin in shipped vials is a trade secret, Plaintiffs request the Court order the Hearing Transcripts, the Swisher Table, and the Certificates of Analysis identified in Exhibit 1 are not confidential and need not be filed under seal when attached to future filings. Plaintiffs further

request the Court order Genentech to produce new versions of those documents without a "Confidential" stamp.

Similarly, Genentech provides no clearly defined and serious injury for making the 2014 FDA-Genentech documents and 2017 FDA General Advice Letter public. Thus, Plaintiffs request the Court order the Dec. 5, 2014 Genentech Response to FDA Comments and the 2017 FDA General Advice Letter are not confidential and need not be filed under seal when attached to future filings. Plaintiffs further request the Court order Genentech to produce new versions of the documents without a "Confidential" stamp. Plaintiffs further request that the 2017 FDA General Advise Letter (Dkt #173-1) be unsealed.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of March, 2017, I electronically transmitted the foregoing document to the Clerk of the Court using the CM/ECF System for filing as required in the Court's Practice and Procedure Order (Dkt. #6 at ¶5).

/s/ David E. Keglovits
David E. Keglovits